

REMARKS

Claims 1-6, 8, 9, 11-15 and 17-26 are pending in the instant application. Claims 1-6, 8, 9, 11, 15, and 17-23 are rejected under the current Office Action, and claims 12-14 and 24-26 are objected to. By this amendment, Claims 1, 11-15, and 23-26 have been amended and claims 8 and 21 have been cancelled, without prejudice to Applicant's rights to pursue the cancelled subject matter in this or related applications. In particular, Claims 1 and 15 have been amended to recite that the EPO is able to protect the excitable tissue without the administration does not increase the hematocrit in said mammal, support for this amendment is found at page 13, ll. 24-26 and page 22, l. 32 to page 23, l. 20 of the current specification. Claims 11 and 23 have been amended to make the claims consistent with the dependant claims, and claims 12-14 and 24-26 have been amended to incorporate the limitations of original claims 1 and 15 respectively to overcome the objection raised by the Examiner. Thus, no new matter has been added by this amendment.

Therefore, claims 1-6, 9, 11-15, 17-20, and 22-26 will be pending upon entry of the instant amendment.

THE REJECTIONS UNDER 35 U.S.C. § 103(a) FOR OBVIOUSNESS IN LIGHT OF FRIEDMAN ET AL. SHOULD BE WITHDRAWN

Claims 1-6, 8, 9, 11, 15 and 17-23 are rejected under 35 U.S.C. § 103(a) as being obvious in light of Friedman et al., American Journal of Kidney Disease, July 26(1):202-8 (1995) (hereinafter "Friedman"). Applicants respectfully disagree with the Examiner's rejection for the reasons outlined below.

To establish a *prima facie* case of obviousness, the teachings of the prior art must provide one of ordinary skill in the art with some suggestion or motivation to make the claimed composition. *In re Rijckaert*, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). For a claimed invention to be deemed obvious in view of a prior art disclosure, the prior art disclosure must, firstly, give rise to a *suggestion of or motivation for* the claimed subject matter. Assuming such a suggestion or motivation is found, and the invention is thus arguably "obvious to try" to achieve, only then does one reach the question of whether one of ordinary skill in the art would have had a reasonable expectation of success in achieving it.

See e.g., In re Vaeck, 947 F.2d 488, 493 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). Both the suggestion of the claimed invention and the expectation of success must be in the prior art, not in the disclosure of the claimed invention. *In re Dow*

Chemical Co., 837 F.2d 469 (Fed. Cir 1988).

The claims, as amended herein, relate to a method of using erythropoietin that does not rely on the sole activity of erythropoietin as recognized in the prior art, *i.e.*, the hematopoietic activity of erythropoietin. Accordingly, the instantly claimed methods are directed to the use of an erythropoietin for the protection of an excitable tissue in a mammal having a neurodegenerative condition, wherein such use of erythropoietin does *not* result in an increase in the hematocrit of said mammal.

In contrast, Friedman discloses the use of erythropoietin exclusively to increase the hematocrit in anemic azotemic diabetic subjects (see Friedman, page 202, second column, lines 27-31). Friedman teaches that the increase of hematocrit also increases the oxygen-transporting capacity of the blood, thereby ameliorating tissue and cellular hypoxia and improving diabetic nephropathy and retinopathy (see Friedman, abstract). Because the improvement of tissue function noted in Friedman is taught to be a result of amelioration of hypoxia and not a direct result of erythropoietin activity, Friedman cannot suggest a method wherein erythropoietin is administered without an increase in the hematocrit of the subject as recited by the instant claims.

Accordingly, Applicants submit that the rejection of claims 1-6, 9, 11-15, 17-20, and 22-26 over Friedman is in error and should be withdrawn.

CONCLUSION

Entry of the foregoing remarks and amendment into the record of the above-identified application is respectfully requested. Applicants estimate that the remarks and amendment made herein now place the pending claims in condition for allowance. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Date: *November 8, 2006*

Respectfully submitted,

Frederick J. Hamble
Frederick J. Hamble

42,623

(Reg. No.)

Warren Pharmaceuticals, Inc.
712 Kitchawan Road
Ossining, NY 10562